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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,484	11/09/2001	Christian Meier	212248US0PCT	5700
22850	7590	12/14/2004	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			SHEIKH, HUMERA N	
			ART UNIT	PAPER NUMBER

1615

DATE MAILED: 12/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/926,484

Applicant(s)

MEIER ET AL.

Examiner

Humera N. Sheikh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 13 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

*James M. Spear*  
JAMES M. SPEAR  
PRIMARY EXAMINER  
AU 1615

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 12/9/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### **Status of the Application**

Receipt of the Preliminary Amendment filed 11/09/01, the Change of Address filed 12/30/02, the Foreign Priority Papers filed 11/09/01 and the Information Disclosure Statements (IDS) filed 02/08/02, 08/23/02, 04/17/03, 05/28/03, 09/08/03 and 10/13/04 is acknowledged.

Claims 1-12 are pending. Claims 2-8 have been amended. New claims 9-12 have been added. Claims 1-12 are rejected.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1, 2, 5, 6 and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Tomoaki *et al.* (JP 01-113322).**

Tomoaki *et al.* disclose an aqueous emulsion consisting of copolymers produced by the emulsion polymerization of (a) an alkyl acrylate (ethyl acrylate), (b) an alkyl methacrylate (methyl methacrylate) and (c) a hydroxyalkyl methacrylate (2-hydroxyethyl methacrylate). A drug containing a specific active component is coated with the emulsion. The ratio of the copolymerized monomers (A/B) is 3:1-1:3 (see Abstract).

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To prepare the emulsion, an emulsifier (sodium dodecyl sulphate – SDS) is dissolved in distilled water and a mixture of monomers is added and emulsified (alkylester acrylate: alkylester methacrylate = 3:1-1:3. The total of alkylester acrylate and alkylester methacrylate: hydroxyalkyl methacrylate = 2:1-10:1. As the alkylester or acrylate: ethyl acrylate, methyl acrylate and butyl acrylate are preferred. As alkylester methacrylate: methyl methacrylate, ethyl methacrylate and butyl methacrylate are preferred. As hydroxyalkyl methacrylate: 2-hydroxymethyl methacrylate is preferred). The mixture is stirred in a stream of nitrogen. A reaction initiating agent as ammonium persulphate (APS) is preferably added and the reaction is continued for a fixed time. During the reaction, APS is added. After the reaction, the mixture solution is filtered to give the desired copolymer emulsion.

Tomoaki *et al.* disclose that coating at a lower temperature than the softening point of the coat is possible. The elution time of a coated drug can also be controlled in a digestive organ, independently of pH.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 3, 4, 7, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tomoaki *et al.* (JP 01-113322).**

Tomoaki *et al.*, as delineated above, teach an aqueous emulsion consisting of copolymers produced by the emulsion polymerization of (a) an alkyl acrylate (ethyl acrylate), (b) an alkyl methacrylate (methyl methacrylate) and (c) a hydroxyalkyl methacrylate (2-hydroxyethyl methacrylate). A drug containing a specific active component is coated with the emulsion. The ratio of the copolymerized monomers (A/B) is 3:1-1:3 (see Abstract).

To prepare the emulsion, an emulsifier (sodium dodecyl sulphate – SDS) is dissolved in distilled water and a mixture of monomers is added and emulsified (alkylester acrylate: alkylester methacrylate = 3:1-1:3. The total of alkylester acrylate and alkylester methacrylate: hydroxyalkyl methacrylate = 2:1-10:1. As the alkylester or acrylate: ethyl acrylate, methyl acrylate and butyl acrylate are preferred. As alkylester methacrylate: methyl methacrylate, ethyl methacrylate and butyl methacrylate are preferred. As hydroxyalkyl methacrylate: 2-hydroxymethyl methacrylate is preferred). The mixture is stirred in a stream of nitrogen. A reaction initiating agent as ammonium persulphate (APS) is preferably added and the reaction is

continued for a fixed time. During the reaction, APS is added. After the reaction, the mixture solution is filtered to give the desired copolymer emulsion.

Tomoaki *et al.* disclose that coating at a lower temperature than the softening point of the coat is possible. The elution time of a coated drug can also be controlled in a digestive organ, independently of pH.

Tomoaki *et al.* teach the incorporation of drug and emulsifier in the emulsion. Tomoaki *et al.* do not explicitly teach a non-ionic emulsifier and drug from the instant selective group. However, it is deemed obvious to one of ordinary skill in the art to employ any suitable emulsifier or drug, based on the desired or intended purpose. The generic 'drug containing specific active component' disclosed by Tomoaki *et al.* would encompass the species of drugs instantly recited.

With respect to the instant amounts and ranges, no criticality is observed in the instant amounts/ranges since one of ordinary skill in this art could readily determine suitable or effective amounts/ranges through the use of routine or manipulative experimentation to obtain the best possible results, as these are indeed variable parameters. Therefore, the instant invention, when considered as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

### Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604.

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The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

H. N. Sheikh *HNS*

Patent Examiner

Art Unit 1615

December 09, 2004

*James M. Spear*  
JAMES M. SPEAR  
PRIMARY EXAMINER  
AU 1615